

Objections**1. To the claims:**

The Examiner objected to the claims stating that there is insufficient antecedent support for the phrases “a defined binding surface” (claim 2) which has been deleted from the amended claims; “bindable derivatives thereof” (claim 4) which has been deleted from claim 4 and other claims containing the objected to phrase; “a permeable material” (claim 7) which has been deleted from claim 7 and changed to “porous”, “wherein the first portion of the first binding species and the second portion of the first binding species, when combined, make up approximately 100% of the known total amount of the first binding species” (claim 12) which has been deleted from claim 12; “wherein binding of first binding species to said second substrate does not impair the binding of first binding species to a binding target” (claim 13) which claim has been cancelled; and “a second substrate having regions characterized by their ability to selectively bind said first binding species if dissociated from said first substrate and regions characterized by their ability to selectively bind first binding species associated with said first substrate” (claim 14) which has been deleted.

In addition, claims 1 and 14 are now more fully described by stating that the binding of the dissociated first binding species to the second substrate does not detrimentally affect the signal strength. Support for this amendment may be found at paragraph 24.

2. To the Specification:

The Examiner objected for the following informalities in the Specification:

On page 12 of 23, the recitation of “lot 1053:89” which has been deleted and In Table 1-6, the recitation of “Level” and “Levels”. Applicants submit that the term “Level” is adequately clear as used in the specification and in light of common knowledge to those of reasonable skill in the art.

Rejections § 112, Second Paragraph

The Examiner rejected claim 1 and other claims as being indefinite. The Examiner asserts that it is not clear how, or by what mechanism, a “region” can bind a binding species. Applicants submit that it is reasonably clear in light of the specification how a “region” can bind a binding species and the specification is replete with examples. See paragraphs [019], [23], [24], [32] and [36]. Regions of the second substrate selectively bind dissociated first binding species.

Applicants respectfully submit that the claim as amended is clear and ask that the rejection be withdrawn.

Applicants respectfully disagree with the Examiner's position regarding the other rejections to claim 1, but believe that the amendments to claim 1 overcome the rejection.

The Examiner rejected claim 2 stating the recitation of "defined" was indefinite. Applicants have deleted this recitation in claims 2, 3, 15 and 16 and ask that the rejection be withdrawn.

The Examiner rejected claim 4 stating that the recitation "selected from the group essentially consisting of" is indefinite. Applications have amended claims 4, 5, and 8 and request that the rejection be withdrawn. The Examiner also rejected claims 4, 5 and 8 stating that the term "bindable derivatives thereof" renders the claims indefinite because it is not clear what binding species are being referred to. Applicants have amended the claim.

The Examiner rejected claim 7 and claims 12, 13 and 14 stating that the term "surface" in claim 7 and the term "region" in claims 12, 13 and 14 rendered the claims indefinite as it was not clear by what mechanism a surface or region could bind a binding species. Applicants submit that these terms are reasonably clear to one of skill in the art when read in light of the specification as to how the surface or region binds a binding species. See the rejection to claim 1 discussed above. Applicants respectfully request that the rejections be withdrawn. In addition, claim 13 has been cancelled without prejudice.

In claims 7, 12 and 14 the Examiner has also rejected the claims stating that conditional "when" or "if" rendered the claim indefinite. Applicants have amended the claims.

In claims 7, 12, and 14 the Examiner rejected the claims stating that the term "dissociated" rendered the claims indefinite as it was not clear what parameters define a state of dissociation or what degree of dissociation is required. Applicants respectfully traverse. The term "dissociated" when read in light of the specification is reasonably clear to one of skill in the art and meets the requirements of the second paragraph of §112.

The Examiner rejected claim 12 stating that the terms "the known total amount" and "make up approximately 100% of the known total amount of the first binding species" lacks antecedent basis. Applicants disagree but have amended the claim.

The Examiner rejected claim 12 stating the term "adapted to" is not clear what parameters of "regions" are modified or what structures correspond to the adaptation. Like the term "region" and "surface" Applicants submit that the term "adapted" when read in the claim and in the light of the specification are clear and that examples are provided as to the

“adaptations” – for example as in the paragraphs set out as examples to the rejection of claim 1 above.

The Examiner rejected claim 14 on the basis of indefiniteness stating that several terms are unclear or lack antecedent basis. The terms “dissociated” and “region” are discussed above. The term “associated” is clear as for the reasons that the term “dissociated” is clear. The terms “their” and “if” have been deleted. The recitations of “a plurality of first binding species to a common second substrate” and “a common second substrate” and “the plurality of first substrate” and “cross-linked” have been deleted.

Applicants submit that the claims as amended meet the requirements of 35 U.S.C. §112, second paragraph and respectfully request that the rejections be withdrawn.

§102 Rejections

The Examiner rejected claims 1-8 and 12-16 as being anticipated by Ullman et al. (US 6,406,913). The Examiner states that Ullman et al. teach a reagent comprising a fluid medium (col. 36, lines 1-32) containing a first substrate (col. 19, lines 47-65) having a first binding species (col. 14, lines 55-67) attached thereto (col. 35, lines 36-38, col. 37, lines 28-35). In addition, the Examiner states that the language “if disassociated from said first substrate” as functional and gives it no weight.

Applicants respectfully traverse. Applicants claim a second substrate having a binding regions that have binding partners capable of selectively binding dissociated first binding species without detrimentally affecting the signal strength of the assay. Ullman et al. is completely opposite. In the competitive format described by Ullman et al. the chemiluminescent solid phase has an associated binding material that reacts with a complementary binding material on the photosensitizer particle. Moreover, the binding of the pair in Ullman et al. relates to assay signal strength. Col. 35, lines 40-45). The language in the claims describes the second substrate and serves to distinguish the claims structurally from Ullman et al.

The Examiner further rejected claim 7 stating that Ullman et al. teaches a reagent comprising a permeable material (col. 19, lines 47-48) including an inner surface having an affinity for said binding species (col. 15, lines 38-40). Applicants traverse. Instead, col. 15, lines 38-40 describes cavities on the binding species not on the permeable (porous) material.

The Examiner rejected claim 12 stating that Ullman et al. teach a reagent used in a sandwich assay comprising a first binding species (col. 37, lines 58+) wherein a first portion (col. 38, lines 7-9) is attached to the first substrate and a second portion is dissociated from the first substrate and the second portion binds to a second substrate. Applicants traverse. Applicants have not found in Ullman et al. where it is disclosed that a second portion of the first binding species is dissociated from the first substrate and then binds to a second substrate.

The Examiner rejected claim 13. Claim 13 has been cancelled. Thus, the rejection is now moot.

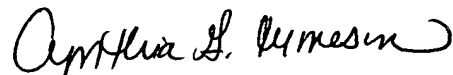
The Examiner rejected claim 14 stating that Ullman et al. teach a reagent wherein specific binding pair members are located on the surface (col. 14, lines 55-56) of different supports and are used in a competitive assay format wherein one binding member is complementary to another binding member (col. 37, lines 28-35).

Applicants respectfully traverse. In the amended claim Applicants claim a second substrate having a binding regions that have binding partners capable of selectively binding dissociated first binding species without detrimentally affecting the signal strength of the assay. Ullman et al. is completely opposite. In the competitive format described by Ullman et al. the chemiluminescent solid phase has an associated binding material that reacts with a complementary binding material on the photosensitizer particle. Moreover, the binding of the pair in Ullman et al. relates to assay signal strength. Col. 35, lines 40-45). The language in the claims describes the second substrate and serves to distinguish the claims structurally from Ullman et al.

Thus, Applicants submit that the claims as amended are not anticipated by Ullman et al. and respectfully request that the rejection be withdrawn.

Applicants submit that the amendments and remarks overcome the Examiner's rejections. The Examiner is encouraged to contact the undersigned if the Examiner has any matter that she would like to address.

Respectfully submitted,



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